

## **REMARKS**

Claims 33 and 39-58 are pending. Claims 1-24 and 31-32 were previously canceled, and claims 25-30 and 34-38 have been canceled herein. Claim 33 has been amended, and new claims 39-58 have been added. Support for the amendments and for the new claims may be found throughout the specification, for example on page 4, lines 10-11 and lines 18-26; on page 5, lines 3-11; in the sections entitled "STUDY 1" *et. seq.*, for example Tables 1 and 4, and page 12, lines 17-19; and on page 20, lines 1-18. No new matter has been added as a result of the amendments or the addition of the new claims.

### **1. Telephone Conference of June 30, 2005**

Applicant thanks the Examiner for taking the time on June 30, 2005 to discuss the instant application with the undersigned representative. Applicant appreciates the Examiner's review of Applicant's proposed claim amendments and new claims, now presented above, and the ensuing discussion of the claims in view of the Guo dissertation cited by the Office in the Office Action mailed April 6, 2005. As discussed, Applicant has set forth the reasons for patentability of the presently pending claims in view of Guo, have provided references to the appropriate passages with the specification to support the amended and new claims, and have provided a Declaration pursuant to 37 CFR §1.132 in support of Applicant's position.

### **2. Claim Rejections – 35 U.S.C. §102**

The Office Action has rejected claims 25-30 and 33-38 under 35 U.S.C. 102(b) as lacking novelty over Guo (Dissertation Abstracts International, 1996, Vol. 57, No. 1B, p. 225) and also as evidenced by Horowitz (US 6,797,267). Specifically, the Office Action asserts that Guo anticipates the claimed invention because Guo teaches HIV infected cells that have been treated with hyaluronidase. Applicant respectfully traverses this rejection.

Nevertheless, solely in order to expedite prosecution, Applicant has amended claim 33 and added new claims 39-48 to more particularly point out and distinctly claim the subject matter of the instant application. Claims 25-30 and 34-37 have been cancelled, thus obviating their rejection. Support for the amendment to Claim 33, and for the new claims, may be found throughout the specification, and in the claims as originally filed. Specifically, support for the amendment to claim 33 may be found, for example, in the specification on page 4, lines 10-11,

on page 5, lines 3-11; in the sections entitled “STUDY 1” *et. seq.*, for example Tables 1 and 4, and page 10, lines 4 and page 12, lines 17-19. Support for new claims 39 and 53 may be found in Table 1. Support for new claims 40-41 and 55 may be found throughout the specification, including in the sections entitled “STUDY 1” *et. seq.* Support for new claims 42, 50, and 57 may be found in the sections entitled “STUDY 1” *et. seq.*, for example page 10, line 12, and in Tables 1-9. Support for new claims 43-44, 46-47, 54, 56, and 58 may be found, for example, on page 12, lines 4-11 and on page 13, second full paragraph. Support for new claim 45 may be found, for example, in originally filed claim 10. Support for new claims 48-49 and 51-52 may be found, for example, in the section entitled “STUDY 1.”

Applicant respectfully contends the claims as pending are fully supported by the specification and are not anticipated by Guo. As the Office has acknowledged (*see* Office Action, page 3, final paragraph), a claimed composition is patentable where it possesses a structural difference over the prior art. Applicant acknowledges that Guo teaches an assay in which HIV infected cells are exposed to hyaluronidase, however Guo is not an anticipatory reference over the presently pending claims as Guo fails to teach the structural limitations of the presently pending claims.

The instant application sets forth the discovery that treatment of HIV infected cells with hyaluronidase at a toxic level (high concentrations and/or for long periods of time) stresses the cells, reduces their viability, and transforms them into HIV immunogens that are capable of initiating the transfer of HIV immunity to naïve cells. In contrast, Guo merely comports with what is known in the prior art, *i.e.* that CD44 is a cell surface receptor for hyaluronic acid, the substrate of hyaluronidase, and that it plays a role in HIV transmission.

Guo fails to teach and every limitation of the pending claims and is therefore not a proper anticipatory reference. For example, Guo fails to teach HIV infected cells that have been treated with hyaluronidase at a toxic concentration. Guo also fails to teach HIV infected cells that have been treated with hyaluronidase for more than one day.

Similarly, Guo fails to teach HIV infected cells treated with hyaluronidase that form HIV immunogens or antigens that prime and activate antigen presenting cells or that exhibit reduced cell viability. Guo clearly does not explicitly teach any of these limitations of the presently pending claims, nor does it do so inherently. Applicant notes that the initial burden with regard to inherency is not his (“In relying upon the theory of inherency, the examiner must provide a

basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)). Nevertheless, Applicant submits herewith the declaration of Damien J. Gallina, BA, BS, RPh pursuant to 37 CFR § 1.132 to support his assertion herein that the presently pending claims are not inherently anticipated by Guo.

As Guo fails to teach or suggest all of the elements of the presently pending claims, Applicant respectfully requests reconsideration of the pending claims and withdraw of the rejection under 35 USC § 102 over Guo.

### CONCLUSIONS

Applicant respectfully contends that all conditions of patentability are met in the pending claims as amended and therefore respectfully request allowance.

If the Examiner believes it to be helpful, the Examiner is invited to contact the undersigned representative by telephone at (312) 913-3349.

Respectfully submitted,  
**McDonnell Boehnen Hulbert & Berghoff LLP**

Dated: 7-6-05

By: Sherri L. Oslick  
Sherri L. Oslick, Ph.D.  
Reg. No. 52,087